

# Congress of the United States

Washington, DC 20515

May 24, 2023

Dr. Robert Califf  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Califf,

Thank you for your efforts to address the growing number of drug shortages across the nation. Amid these ongoing challenges, we are especially concerned about the nationwide shortage of chemotherapy medications and urge the U.S. Food and Drug Administration (FDA) to immediately act to mitigate its effects.

The FDA is currently reporting a nationwide shortage of cisplatin and carboplatin, two essential chemotherapy drugs that are often used to treat lung, gynecologic, and breast cancers. The shortage of cisplatin was reported by the FDA on February 10, 2023, followed by the shortage of carboplatin on April 28, 2023.<sup>1</sup> The FDA also reported a shortage of methotrexate, a chemotherapy drug used in the treatment of several types of cancer, on March 13, 2023.<sup>2</sup>

These chemotherapy drug shortages come amid a shortage of other critical cancer medications. Taken together, they are straining the ability of doctors to provide the best course of treatment for their patients. We are hearing directly from impacted hospitals urging immediate action to address these alarming challenges.

Patients should not have to worry whether they can access the scarce chemotherapy drugs they need on top of the daily stressors accompanied by a cancer diagnosis. But in the wake of these shortages, doctors and patients are being forced to make difficult decisions to turn to alternative treatments that could result in worse outcomes.

We understand these shortages have been fueled, in part, by a halt in production at Intas Pharmaceuticals – an India-based company that manufactures methotrexate, carboplatin, and cisplatin – after FDA inspectors identified quality-control violations.<sup>3</sup> We appreciate the robust oversight the FDA conducts to ensure medications received from overseas facilities are held to high quality standards, but more must be done to ease the troubling supply disruptions that also put patients at risk.

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<sup>1</sup>[https://www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Cisplatin%20Injection&st=c](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cisplatin%20Injection&st=c);

[https://www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Carboplatin%20Injection&st=c](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Carboplatin%20Injection&st=c)

<sup>2</sup>[https://www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Methotrexate%20Injection&st=c](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Methotrexate%20Injection&st=c)

<sup>3</sup><https://www.pharmacompass.com/pdf/news/fda-issues-form-483-to-intas-pharma-21077.pdf>

For these reasons, we request an immediate briefing from FDA on the situation and written answers on the following questions:

1. How is the FDA working with manufacturers to mitigate the shortage of chemotherapy drugs cisplatin, carboplatin, and methotrexate?
2. As doctors and patients continue turning to alternative drugs, should we expect additional shortages of other chemotherapy drugs?
3. What flexibilities can the FDA provide to help manufacturers swiftly increase their production of cisplatin, carboplatin, and methotrexate?
4. When does the FDA anticipate the chemotherapy drug shortage to alleviate?
5. How is FDA leveraging temporary importation and other flexibilities to work with industry on bringing other manufacturers into the market to alleviate the shortages of cisplatin, carboplatin, and methotrexate?

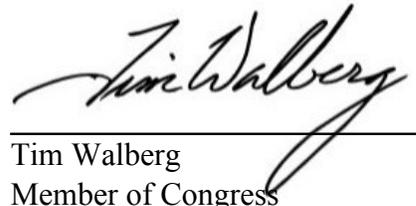
Thank you for your attention to this critical issue. We look forward to continuing to work together to ensure the FDA can better anticipate, mitigate, and alleviate drug shortages.

Sincerely,



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Debbie Dingell  
Member of Congress



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Tim Walberg  
Member of Congress



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Bill Huizenga  
Member of Congress



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Rashida Tlaib  
Member of Congress



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Daniel T. Kildee  
Member of Congress



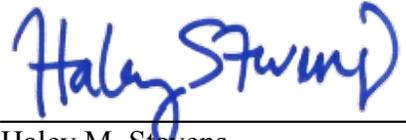
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Shri Thanedar  
Member of Congress



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Elissa Slotkin  
Member of Congress



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Haley M. Stevens  
Member of Congress



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Hillary J. Scholten  
Member of Congress



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John James  
Member of Congress



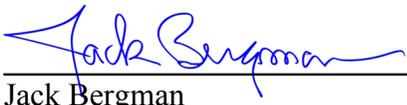
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John R. Moolenaar  
Member of Congress



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Lisa C. McClain  
Member of Congress



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Jack Bergman  
Member of Congress